UNIVERSITY
OF MIAMI
ETHICS PROGRAMS

Implementing U.S. Federal Standards in International Research (Latin America and the Caribbean)

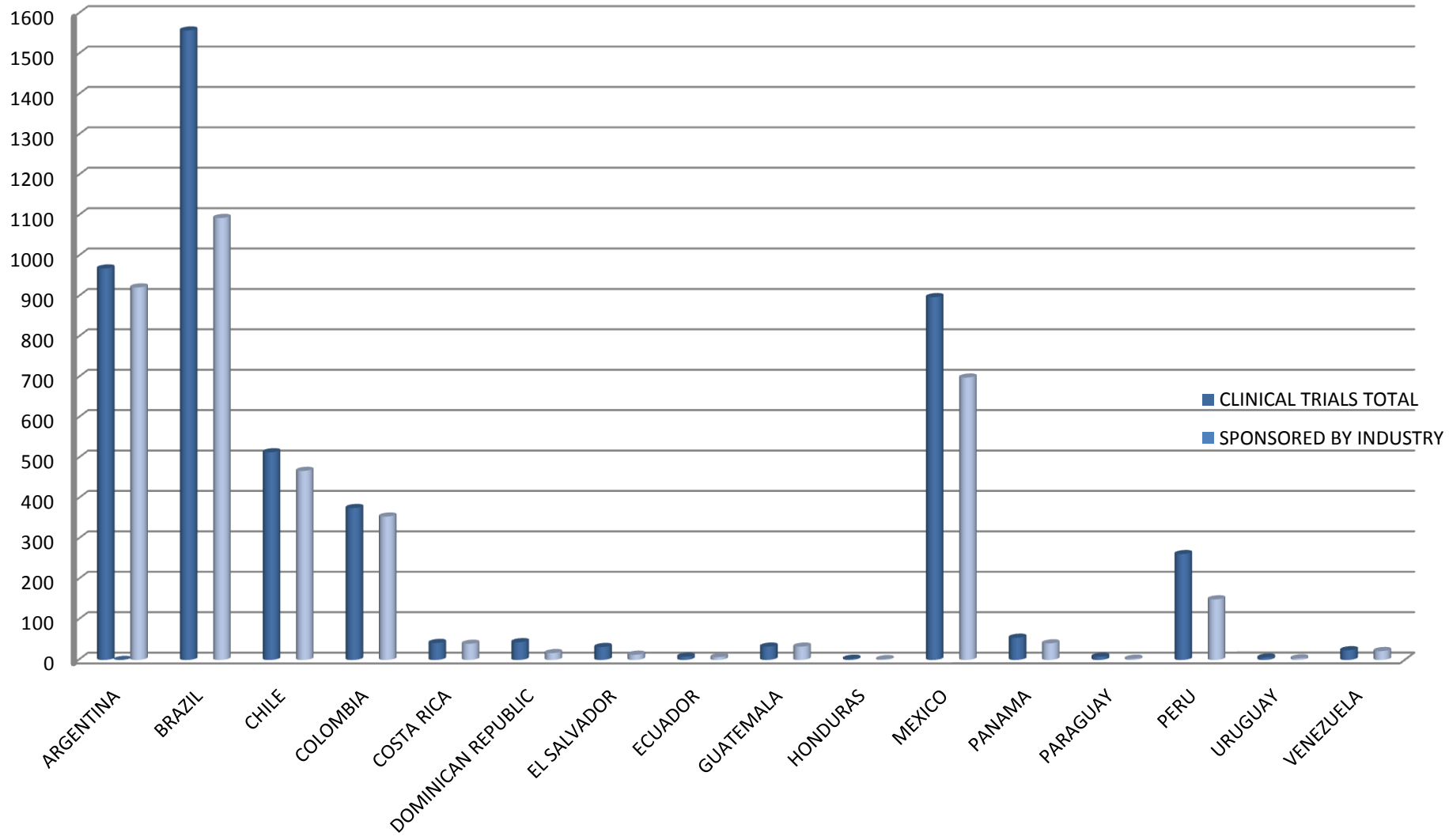
Presidential Commission for the Study of Bioethical Issues

May 18th 2011

Sergio Litewka M.D.M.P.H
University of Miami Ethics Programs

Panamerican PABI Bioethics Initiative

Clinical Trials in Latin America
January 1st 2005- April 1st 2011
Source : Clinicaltrials.gov



Cultural and logistical challenges in the Latin American and Caribbean scenario

- Informed consent
  - Legal information may be excessive and confusing
  - Adequate disclosure of risks and eventual benefits
  - Risk of therapeutic misunderstanding
- IRBs
  - Definition of exempt studies
  - Lack of resources
  - Clinical Ethics Committees acting as Research Ethics Committees
  - Conflicts of interests- IRB independence
  - Deficiencies in assuring privacy and confidentiality
  - Oversight of clinical trials

Challenges for implementing Federal standards in international research (Latin America and the Caribbean)

- Absence of specific regulations for the protection of human subjects (Caribbean and some Central American countries)
- Insufficient regulations
- Overlapping guidelines and regulations
- Weak enforcement of human subject protections regulations
- Scarce resources devoted to the oversight of clinical trials

Other challenges

- Accountability of the investigator and/or the foreign institution
- Transparency
- Lack of public trust in the research enterprise
- Use of placebos
- Definition of vulnerability
- Governance